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10/597,813

04/13/2007

Ulrich Bogdahn

JCLA21512

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EXAMINER

GIBBS, TERRA C

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/597,813 | Applicant(s) BOGDAHN ET AL. | |
| | Examiner TERRA C. GIBBS | Art Unit 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

SUPPLEMENTAL RESTRICTION REQUIREMENT

This Office Action is a response to the previous Restriction Requirement mailed March 17, 2008.

It is noted that in the previous Restriction Requirement mailed March 17, 2008, claims 1-12 were indicated as needing a restriction requirement. However, the Examiner inadvertently failed to notice that claims 1-12 were canceled in the amendment filed August 8, 2006, and new claims 13-39 were added. In this regard, the previous Restriction Requirement mailed March 17, 2008 is rescinded in view of the instant Restriction Requirement.

Claims 1-12 have been canceled. New claims 13-39 are acknowledged.

Claims 13-39 are pending.

Claims 13-39 are subject to restriction as detailed below:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 13, 16-18, drawn to an oligonucleotide selected from the group comprising SEQ ID NO:3 and elongated sequences of SEQ ID NO:3 which can be represented by the general formula, 5'-XCAGCCCCCGACCCATGZ-3'. **If this Group is elected, a further restriction is required as detailed below.**

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Group II, claim(s) 14 and 15, drawn to an oligonucleotide selected from the group comprising SEQ ID NO:3 to SEQ ID NO:32 and SEQ ID NO:34 to SEQ ID NO:72. **If this Group is elected, a further restriction is required as detailed below.**

Group III, claims 19-25, drawn to the use of at least one oligonucleotide having a sequence at least 80% identical to a subsequence of SEQ ID NO:1 or SEQ ID NO:2. **If this Group is elected, a further restriction is required as detailed below.**

Group IV, claim 26, drawn to a method for identifying a compound interfering with a biological activity of TGF-R_{II} or the expression of TGF-R_{II}.

Group V, claims 26 and 39, drawn to a method for identifying a compound interfering with a biological activity of TGF- β 1/TGF-R signaling.

Group VI, claims 27-32, drawn to an oligonucleotide having sequence at least 80% identical to a subsequence of SEQ ID NO:94 or SEQ ID NO:95 or SEQ ID NO:96. **If this Group is elected, a further restriction is required as detailed below.**

Group VII, claims 33-38, drawn to the use of an oligonucleotide having sequence at least 80% identical to a subsequence of SEQ ID NO:94 or SEQ ID NO:95 or SEQ ID NO:96 as well as mimetics and variants thereof. **If this Group is elected, a further restriction is required as detailed below.**

Group VIII, claim 39, drawn to a method for identifying a compound interfering with a biological activity of TGF-R_I or the expression of TGF-R_I.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed oligonucleotides, the Markush group shall be regarded as being of similar nature when:

(A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all

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alternatives belong to an art-recognized class of compounds in the art to which the invention pertains.

The oligonucleotides that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II}, and mimetics, variants, salts and optical isomers thereof in claim 13 do not meet the criteria of (B)(1), where a common structure is present, i.e., a significant structure is shared by all of the alternatives. The oligonucleotides listed in claims 14 and 15 do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the oligonucleotides listed in claim 13 is lacking and each oligonucleotide capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II}, and mimetics, variants, salts and optical isomers thereof claimed is considered to constitute a special technical feature.

Furthermore, if Group I is elected, claim 13 is subject to restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02- PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334

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(CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 13 specifically claim an oligonucleotide selected from the group comprising SEQ ID NO:3 and elongated sequences of SEQ ID NO:3 which can be represented by the general formula, 5'-XCAGCCCCCGACCCATGZ-3'. Although the oligonucleotides claimed are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II}, and mimetics, variants, salts and optical isomers thereof, the instant oligonucleotides are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide sequence has a unique nucleotide sequence (per Applicant's disclosure at pages 13-16 in the specification). As such the Markush/genus of oligonucleotide sequences in claim 13 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the oligonucleotide sequences claimed in claim 13 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed oligonucleotide sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for

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examination. Accordingly, applicants are required to elect one (1) **X oligonucleotide sequence** and one (1) **Z oligonucleotide sequence** from claim 13. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct nucleotide sequences.

The oligonucleotides that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II} or a region of the mRNA encoding TGF-R_{II} and mimetics, variants, salts and optical isomers thereof in claims 14 and 15 do not meet the criteria of (B)(1), where a common structure is present, i.e., a significant structure is shared by all of the alternatives. The oligonucleotides listed in claims 14 and 15 do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the oligonucleotides listed in claims 14 and 15 is lacking and that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II} or a region of the mRNA encoding TGF-R_{II} and mimetics, variants, salts and optical isomers thereof claimed is considered to constitute a special technical feature.

Furthermore, if Group II is elected, claims 14 and 15 are subject to restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02-PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the

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entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 14 and 15 specifically claim drawn to an oligonucleotide selected from the group comprising SEQ ID NO:3 to SEQ ID NO:32 and SEQ ID NO:34 to SEQ ID NO:72. Although the oligonucleotides claimed are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II} or a region of the mRNA encoding TGF-R_{II} and mimetics, variants, salts and optical isomers thereof, the instant oligonucleotides are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide sequence has a unique nucleotide sequence (per Applicant's disclosure at pages 13-16 in the specification). As such the Markush/genus of oligonucleotide sequences in claims 14 and 15 is not considered to constitute a proper genus, and is therefore

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subject to restriction. Furthermore, a search of more than one (1) of the oligonucleotide sequences claimed in claims 14 and 15 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed oligonucleotide sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) oligonucleotide from claims 14 and 15. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct nucleotide sequences.

The use of the oligonucleotides that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II} or a region of the mRNA encoding TGF-R_{II} and mimetics, variants, salts and optical isomers thereof in claim 19 do not meet the criteria of (B)(1), where a common structure is present, i.e., a significant structure is shared by all of the alternatives. The use of the oligonucleotides listed in claim 19 does not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the use of the oligonucleotides listed in claim 19 is lacking and that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II} or a region of the mRNA encoding TGF-R_{II} and mimetics, variants, salts and optical

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isomers thereof claimed is considered to constitute a special technical feature.

Furthermore, if Group III is elected, claim 19 is subject to restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02- PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 19 specifically claims the use of at least one oligonucleotide having a sequence at least 80% identical to a subsequence of SEQ ID NO:1 or SEQ ID NO:2. Although the use of the oligonucleotides claimed are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_{II} or a region of the mRNA encoding TGF-R_{II} and mimetics, variants, salts and optical isomers thereof, the instant oligonucleotides are considered

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to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide sequence has a unique nucleotide sequence (per Applicant's disclosure at pages 13-16 in the specification). As such the Markush/genus of use of oligonucleotide sequences in claim 19 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the uses of oligonucleotide sequences claimed in claim 19 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed oligonucleotide sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) oligonucleotide from claim 19. That is, Applicants are required to elect either SEQ ID NO:1 or SEQ ID NO:2 from claim 19. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct nucleotide sequences.

The oligonucleotides that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_I or a region of the mRNA encoding TGF-R_I and mimetics, variants, salts and optical isomers thereof in claims 27-29 do not meet the criteria of (B)(1), where a common structure is present, i.e., a significant structure is shared by all of the alternatives. The oligonucleotides listed in claim 27-29 do not meet the criteria of (B)(1),

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as they do not share, one with another, a common core structure. Accordingly, unity of invention between the oligonucleotides listed in claim 27-29 is lacking and that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_I or a region of the mRNA encoding TGF-R_I and mimetics, variants, salts and optical isomers thereof claimed is considered to constitute a special technical feature.

Furthermore, if Group VI is elected, claims 27-29 are subject to restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02- PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 27-29 specifically claims an oligonucleotide having sequence at least

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80% identical to a subsequence of SEQ ID NO:94 or SEQ ID NO:95 or SEQ ID NO:96. Although the oligonucleotides claimed are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_I or a region of the mRNA encoding TGF-R_I and mimetics, variants, salts and optical isomers thereof, the instant oligonucleotides are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide sequence has a unique nucleotide sequence (per Applicant's disclosure at pages 13-16 in the specification). As such the Markush/genus of oligonucleotide sequences in claims 27-29 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the oligonucleotide sequences claimed in claims 27-29 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed oligonucleotide sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) oligonucleotide from claims 27 and 28. That is, Applicants are required to elect either SEQ ID NO:94, or SEQ ID NO:95, or SEQ ID NO:96 from claims 27 and 28. Further, Applicants are required to elect one (1) oligonucleotide from claim 29. It is noted that the sequence that Applicants elect from claim 27 and 28 **must correspond** with the sequence elected from claim 29. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct

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nucleotide sequences.

The use of the oligonucleotides that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_i or a region of the mRNA encoding TGF-R_i and mimetics, variants, salts and optical isomers thereof in claim 33 do not meet the criteria of (B)(1), where a common structure is present, i.e., a significant structure is shared by all of the alternatives. The use of the oligonucleotides listed in claim 33 does not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the use of the oligonucleotides listed in claim 33 is lacking and that are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_i or a region of the mRNA encoding TGF-R_i and mimetics, variants, salts and optical isomers thereof claimed is considered to constitute a special technical feature.

Furthermore, if Group VII is elected, claim 33 is subject to restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02- PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure

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described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 33 specifically claims the use of an oligonucleotide having sequence at least 80% identical to a subsequence of SEQ ID NO:94 or SEQ ID NO:95 or SEQ ID NO:96 as well as mimetics and variants thereof. Although the use of the oligonucleotides claimed are capable of hybridizing sufficiently with the region encompassing the translation initiation codon of the open reading frame of the gene encoding TGF-R_I or a region of the mRNA encoding TGF-R_I and mimetics, variants, salts and optical isomers thereof, the instant oligonucleotides are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide sequence has a unique nucleotide sequence (per Applicant's disclosure at pages 13-16 in the specification). As such the Markush/genus of use of oligonucleotide sequences in claim 33 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the uses of oligonucleotide sequences claimed in claim 33 presents an undue burden on the Patent and Trademark Office due

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to the complex nature of the search and corresponding examination of more than one (1) of the claimed oligonucleotide sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) oligonucleotide from claim 33. That is, Applicants are required to elect either SEQ ID NO:94, or SEQ ID NO:95, or SEQ ID NO:96 from claim 33. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct nucleotide sequences.

The method for identifying a compound interfering with a biological activity of TGF-R_{II} or the expression of TGF-R_{II} and the method for identifying a compound interfering with a biological activity of TGF-R_I or the expression of TGF-R_I listed in Groups IV and VIII, respectively do not meet the criteria of (B)(1), where a common structure is present, i.e., a significant structure is shared by all of the alternatives. The special technical feature of the method for identifying a compound interfering with a biological activity of TGF-R_{II} or the expression of TGF-R_{II} and the method for identifying a compound interfering with a biological activity of TGF-R_I or the expression of TGF-R_I listed in Groups IV and VIII, respectively do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the method for identifying a compound interfering with a biological activity of TGF-R_{II} or the expression of TGF-R_{II} and the method for identifying a compound

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interfering with a biological activity of TGF-R_I or the expression of TGF-R_I listed in Groups IV and VIII, respectively is lacking and each special technical feature claimed is considered to constitute a special technical feature.

Thus, in summary, each of Groups IV and VIII is directed to different special technical features, namely the use of distinct and independent compounds, and thus supports this lack of unity.

The methods for identifying a compound interfering with a biological activity of TGF-R_I/TGF-R_{II} or the expression of TGF-R_I/TGF-R_{II} of Groups IV and VIII and the method for identifying a compound interfering with a biological activity of TGF- β 1/TGF-R signaling listed in Group V do not meet the criteria of (B)(1), where a common structure is present, i.e., a significant structure is shared by all of the alternatives. The special technical feature of methods for identifying a compound interfering with a biological activity of TGF-R_I/TGF-R_{II} or the expression of TGF-R_I/TGF-R_{II} of Groups IV and VIII and the method for identifying a compound interfering with a biological activity of TGF- β 1/TGF-R signaling listed in Group V do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the methods for identifying a compound interfering with a biological activity of TGF-R_I/TGF-R_{II} or the expression of TGF-R_I/TGF-R_{II} of Groups IV and VIII and the method for identifying a compound interfering with a biological activity of TGF- β 1/TGF-R signaling listed in Group V is lacking and each special technical feature claimed is

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considered to constitute a special technical feature.

Thus, in summary, Groups IV and VIII is directed to different special technical features from Group V, namely the use of distinct and independent compounds, and thus supports this lack of unity.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERRA C. GIBBS whose telephone number is (571) 272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check


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PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

September 2, 2008

/Terra Cotta Gibbs/

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| <div>Application Number</div> <div></div> | Application/Control No. | Applicant(s)/Patent under Reexamination | |
| | 10/597,813 | BOGDAHN ET AL. | |
| | Examiner | Art Unit | |
| | TERRA C. GIBBS | 1635 | |